No. 84-130

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In The

Supreme Court of the United States

October Term, 1984

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

vs.

ROCHE PRODUCTS, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR THE GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION AS AMICUS CURIAE

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PRELIMINARY STATEMENT

This amicus brief is presented by the Generic Pharmaceutical Industry Association pursuant to Rule 36.1 of the Supreme Court Rules with the written consent of both parties on file with the Clerk of this Court. This brief supports the petition of Bolar

Pharmaceutical Co., Inc. that a writ of certiorari issue to review the decision of the Court of Appeals for the Federal Circuit which was entered on April 23, 1984.

INTEREST OF AMICUS CURIAE

The Generic Pharmaceutical Industry Association (GPIA) was formed in 1980 by a group of independent generic drug manufacturers, distributors and retailers. It now includes about 85% of the independent generic drug industry, and represents the interests of that industry in legislative, judicial and administrative forums.

The prescription drug products marketed by GPIA members must be approved by the Food and Drug Administration (FDA) with respect to safety and effectiveness before those products may be manufactured and sold.[1] This pre-marketing approval requirement applies to essentially all prescription drug products, including generic drugs, *i.e.*, drugs which are the chemical and therapeutic equivalent of an existing and previously approved brand name drug product. Under FDA regulations, a GPIA member company seeking approval to sell a generic version of a previously marketed brand name drug product must develop and submit data to the FDA sufficient to establish that the generic drug product can be commercially produced in a chemically stable form and that the active drug ingredient gets into the body in the same amount and at the same speed as the existing brand name product. It is generally recognized that at least about two (2) years will elapse between the date when a company first decides to market a new generic drug and the date of actual FDA approval.

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1. Federal Food Drug and Cosmetic Act, 21 U.S.C. §321, *et seq.*

The sale of a drug product without such approval is a crime, and the products are subject to seizure.[2]

The decision below holds Bolar liable for patent infringement based solely on the pre-patent expiration testing activities which were undertaken to obtain FDA approval to market a generic version of flurazepam hydrochloride. It is beyond dispute that none of Bolar's testing activities prior to the patent expiration date reduced Roche's market by a single tablet during the life of the Roche patent. Indeed, none of those activities resulted in the production of a single tablet which was used or sold for therapeutic purposes either before or after the patent expiration date. In short, Bolar sought only to place itself in a position to engage in legitimate competition with Roche at the earliest possible date after the Roche patent expired without depriving Roche of any of the economic benefits of its patent rights prior to that expiration date.

The decision of the Federal Circuit has a substantial adverse impact which extends well beyond the specific parties and drug product involved in this litigation. It upsets the common and long-standing testing practices of generic drug manufacturers and promises to spawn a significant amount of unwarranted litigation with respect to past testing activities which everyone believed to be permissible. Until this case, no drug patent owner ever sought to prevent FDA testing prior to patent expiration even though it was well known that such testing was common and drug patent infringement claims were otherwise being vigorously pursued. This new wave of litigation (which has already begun) is designed and intended to wrongfully extend the effective life of a patent monopoly beyond its expiration date, thereby frustrating the "limited" monopoly provisions of the Constitution, this Court's

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2. *United States v. Generix Drug Sales Inc.*, ____ U.S. ____, 75 L. Ed. 2d 198 (1983).

rigorous adherence to the constitutional concept of a time limited monopoly, and the public policy favoring the availability of lower costing generic drugs.[3]

SUMMARY OF ARGUMENT

The purpose of the patent law is to provide incentives for creative effort, but a use of a patented invention that has no demonstrable effect on the potential market for, or value of, the patented invention need not be prohibited to protect that incentive. This principle was recently reaffirmed by this Court in a copyright case[4] and applies with equal force to patents, since both forms of intellectual property have a common constitutional origin and purpose. Indeed, the judicially developed doctrine of *de minimis* or experimental use in patent cases is completely analogous to the "fair use" doctrine of copyright law and both doctrines should logically be governed by a common set of principles. Those principles establish that testing activities which in no way diminish the patent owner's ability to profit from the demand for the patented invention during the life of a patent are not actionable even though they may, in a purely technical sense, infringe on the statutory rights granted to the patent owner.

The Federal Circuit failed to reach the right conclusion in this case only because it literally construed the word "use" in the patent law and placed unwarranted emphasis on the ultimate post-patent expiration commercial purpose of Bolar's experiments. In so doing, it disregarded the fact that Bolar's testing activity

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3. Staff Report to the Federal Trade Commission, Drug Product Selection (1979); Warner, *Consumer Protection and Prescription Drugs: The Generic Substitution Laws,* 67 Kentucky Law Journal 389 (1979).

4. *Sony Corp. of America v. Universal City Studios, Inc.,* ___ U.S. ___ (1984).

did not in any way diminish the market for the patented Roche drug during the life of the Roche patent and that Roche lost no profits and suffered no other injury whatsoever during the life of its patent. The Constitution commands that the patent monopoly last for only a limited time and that the public may then enjoy full access to the patented invention. By relying on Bolar's commercial intentions after the Roche patent expired rather than focusing on Bolar's activities during the life of the patent, the Federal Circuit improperly extended the effective life of the Roche patent.

In reaching its erroneous decision, the Federal Circuit ignored the best evidence that FDA testing causes no injury and should not be actionable. That evidence consists of the failure of Roche and other drug patent owners to ever before assert a patent infringement claim based on FDA testing activities or to even seek damages or other relief for such testing activities in proven cases of commercial patent infringement. Despite the zealous enforcement of patent rights by drug patent owners, no reported case involving the enforcement of a drug patent grants any relief with respect to any acts undertaken by an infringing generic company to obtain FDA approval to market a drug covered by an unexpired patent. That such approvals have been routinely sought and granted for many years is common knowledge in the pharmaceutical industry. Indeed, prior to the present case, even Roche publicly took the position that seeking FDA approval to market a patented drug product was a legitimate activity and not an act of patent infringement. It took that position in a case involving Valium, the most financially important drug in the recent history of Roche.

ARGUMENT

I.

Bolar's acts are not an infringing use of the patented invention.

The grant of a patent conveys the right "to exclude others from making, using or selling the invention. . . " 35 U.S.C. §154. This Court has characterized that right as the "right to be free from competition in the practice of the invention." *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944); *see also, Kaz Manufacturing Co., Inc v. Chesebrough-Ponds, Inc.*, 317 F.2d 679 (2d Cir. 1963). Put another way, a patent "insures against another doing substantially the same thing in substantially the same way as the patentee." 69 C.J.S. *Patents*, p. 172, quoted in *Kaz Manufacturing Co., Inc. v. Chesebrough-Ponds, Inc.*, 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd*, 317 F.2d 679 (2d Cir. 1963).

The crucial factor historically relied on by courts in determining whether a charged activity constitutes "use" within the meaning and intent of the patent laws, is the purpose and effect of the use. The courts have consistently upheld the public's right to use a patented article for purposes which do not disturb the patentee's enjoyment of the exclusive privileges secured by a patent while variously characterizing such accused, but non-infringing uses, as *de minimis*, experimental, outside the scope of the patent or in the public interest. *Kaz Manufacturing Co., Inc. v. Chesebrough-Ponds, Inc., supra; Celotex Corporation v. V.E. Power Door Corp*, 204 U.S.P.Q. 636 (E.D.N.Y. 1979); *Levin v. Ripple Twist Mills*, 416 F. Supp. 876 (E.D. Pa. 1976), *dismissed without opinion*, 549 F.2d 795 (3rd Cir. 1976); *Akro Agate Company v. Master Marble Company*, 18 F. Supp. 305 (N.D.W.Va. 1937); *Maxon Premix Burner Company, Inc. v. Eclipse Fuel Engineering Co.*, 471 F.2d 308 (7th Cir. 1972).

The foregoing principles, which collectively establish that not every literal "use" of a patented invention amounts to patent infringement, were succinctly summarized almost 100 years ago in 3 Robinson, *The Law of Patents for Useful Inventions*, §898 (1890) as follows:

> "The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of pecuniary character. . . . Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one."

Recently, this Court had the opportunity to evaluate the question of whether every literal "use" of a copyrighted work constitutes infringement or whether there are certain "fair uses" which carry no such liability. *Sony Corp. of America v. Universal City Studios, Inc.*, ____ U.S .____(1984). In language strongly supportive of the Robinson patent textbook, this Court held:

> "The purpose of copyright is to create incentives for creative effort. Even copying for non-commercial purposes may impair the copyright holder's ability to obtain the rewards that Congress intended him to have. But a use that has no demonstrable effect upon the potential market for, or the value of, the copyrighted work need not be prohibited in order to protect the author's incentive to create. The prohibition of such noncommercial uses wouuld merely inhibit access to ideas without any countervailing benefit."

The striking similarity between the "fair use" doctrine in copyright law and the experimental or *de minimis* use doctine in patent law is no accident. Rather it is the natural outgrowth of the fact that both forms of intellectual property are derived from the same constitutional provision (Article 1, Section 8) and the consistent recognition by this Court of the special and limited nature of these intellectual property monopolies. As this Court stated in *Sony* with respect to both patents and copyrights:

> "The monoply privileges that Congress may authorize are neither unlimited nor primarily designed to provide a special private benefit. Rather, the limited grant is a means by which an important public purpose may be achieved. It is intended to motivate the creative activity of authors and inventors by the provision of a special reward, and to allow the public access to the products of their genius after the limited period of exclusive control has expired."

Clearly, both the "fair use" and "experimental use" doctrines are merely a prudent judicial attempt to augment the efforts of Congress in striking the appropriate balance between the competing interests of authors or inventors on the one hand and the public on the other.

The Federal Circuit, while giving lip service to all of the foregoing principles, nevertheless gave a literal construction to the word "use" in Section 271 of the Patent Law. It permitted itself to be unduly influenced by the fact that Bolar's purpose in doing FDA testing was to ultimately engage in a commercial enterprise while totally failing to consider the fact that this commerce would not begin until long after the Roche patent expired. The Circuit Court failed to recognize that the FDA testing activities of Bolar and Bolar's eventual manufacture and sale of

the drug after receiving FDA approval are distinct events which are separated by an even more important event — the expiration of the Roche patent.

The pre-expiration testing activities do not injure Roche because, as in *Sony,* they have no demonstrable effect on the market for, or value of the patented invention during the life of the Roche patent. The eventual competitive commercial activities of Bolar in making, using and selling the drug product after receiving FDA approval are not wrongful and cannot be the cause of any legally cognizable injury to Roche because those activities do not occur until after the Roche patent has expired! The Federal Circuit simply failed to draw the necessary and proper distinction between Bolar's non-infringing acts prior to patent expiration, which are themselves non-injurious, but are designed to hasten legitimate competition after the Roche patent expires, and the commercial acts of Bolar subsequent to patent expiration, which are not acts of infringement because the Roche patent has expired. There is no proper analogy to the so-called "stockpiling" cases[5] because those cases involve an actual act of infringement during the life of a patent, namely, the commercial manufacture of the patented invention. Here, not a single tablet made by Bolar prior to patent expiration will be sold or used for therapeutic purposes either before patent expiration or afterward.

The Federal Circuit also failed to recognize that FDA approval does not require Bolar to engage in commercial manufacture, use or sale of the approved drug product. It merely provides Bolar with the privilege of doing so. If Bolar obtained FDA approval during the first year of the Roche patent and thereafter engaged in no other activity for sixteen (16) years until the patent expired,

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5. *See, e.g., Underwood Typewriter Co. v. Elliott-Fisher Co.,* 156 F. 588 (C.C. S.D.N.Y. 1907).

its actions would clearly be characterized as *de minimis* on the ground that they amounted to nothing more than an activity which was terminated before it had advanced to a stage where it invaded the patentee's exclusive rights. *Cf., Imperial Chemical Industries, PLC v. Henkel Corporation,* 545 F. Supp. 635 (D. Del. 1982); *Maxon Premix Burner Company, Inc. v. Eclipse Engineering Co., supra; Finney v. United States,* 194 U.S.P.Q. 197 (Ct. Cl. 1976). The acts involved in obtaining FDA approval and commercialization will follow each other without interruption in this case solely because the Roche patent will expire by the time FDA approval is obtained. Surely, the fact that Roche's patent was about to expire did not give Roche greater rights or change the *de minimis* character of Bolar's pre-expiration acts. Preparation for legitimate competition is not infringement and cannot properly be combined with activities following patent expiration so as to reach a contrary conclusion. Indeed, any protection against post-expiration competition is contrary to established federal policy. As this Court stated in *Scott Paper Co. v. Marcalus Co.,* 326 U.S. 249, 256 (1964):

> ". . . any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws."

See also, Brulotte v. Thys Co., 379 U.S. 29 (1964).

In the final analysis, the Federal Circuit placed unwarranted emphasis on the fact that Bolar will benefit from its FDA testing activities because it will be able to compete with Roche at an earlier date after the patent expires. But, FDA pre-marketing approval regulations were enacted to protect the health and safety of the public and not for the purpose of extending the life of patent monopolies. *Upjohn Mfg. Co. v. Schwerker,* 681 F. 2d 480 (6th

Cir. 1982). Roche has no standing to complain about when, where or how Bolar satisfies FDA requirements or commences competition, provided that Roche is free of competition during the life of the Roche patent.

The District Court below correctly perceived the significance of all of the foregoing facts and made the following holding:

> "More importantly, the court cannot find a basis for holding that Bolar's limited experimental use of flurazepam hcl would constitute infringement. First, Bolar realizes no benefit during the term of the patent; its activities are in no way connected with current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent's term. Second, post-expiration delay in competition unintentionally imposed by FDA regulation is not a right or benefit granted by the patent law. This court will not act to protect a right or benefit that is without legal basis. Third, Roche can point to no substantial harm it will suffer from Bolar's FDA studies before the patent expires. Bolar's threatened activity is at best *de minimis* and will not support an action for infringement."

The District Court should have been affirmed.

II.

The lack of economic harm is confirmed by the past inaction of Roche and other drug patent owners.

The Federal Circuit decision below upsets the long prevailing pharmaceutical industry practice of conducting required FDA testing prior to patent expiration. Appendix A hereto is a small

sample of publicly available information which establishes (based on FDA filing and approval dates and patent expiration dates) that such testing has been common. In reviewing this exemplary but non-exhaustive list, it is of more than passing interest that it includes Librium (a Roche product) and other products which have been involved in patent infringement litigation. Yet, none of those cases[6] involved any request for (or grant of) relief aimed at the FDA testing activities of the infringer. Certainly, there was no effort by Roche, as there is here, to seek an order destroying FDA test data or otherwise prohibiting its use.

Any doubt about the unprecedented nature of the Federal Circuit's decision in this case will be quickly put to rest by considering the statements and actions of Roche with respect to the FDA testing activities in a case which involved the alleged infringement of the patent covering Roche's most financially important product — Valium. In *Hoffman-LaRoche, Inc. v. Zenith Laboratories, Inc.*, Civil Action No. 75-2221 (D.N.J.), Zenith sought a declaratory judgment dismissing Roche's claim that its patent covering Valium was infringed on the ground that it had only engaged in FDA testing activities and that such activities did not constitute infringement. In a memorandum in support of a Rule 12 motion seeking to dismiss Zenith's counterclaim, Roche stated:

> "It has been clear from the outset of this case that *Roche does not seek to interfere with Zenith's legitimate activities in seeking F.D.A. approval of a New Drug Application (NDA) for diazepam.* Nor has Roche done anything to interfere with Zenith's bidding for U.S. government contracts. Roche's

6. *Hoffmann-LaRoche Inc. v. Zenith Laboratories, Inc.*, Civil Action No. 75-96 (D.N.J.) (Librium); *Eli Lilly v. Generix Drug Sales Inc.*, 324 F. Supp. 715 (S.D. Fla. 1971) (Darvon).

> brief in opposition to Zenith's Rule 12 motion expressly states:
>
> 'Roche does not seek to enjoin Zenith from doing the experimental work necessary for it to secure F.D.A. approval or from bidding for U.S. government contracts.' (p. 5)." (Emphasis added.)

A consent judgment which was subsequently entered in the foregoing Valium case (Appendix B) contains an express acknowledgment of Zenith's prior FDA testing activity as well as Zenith's intention to continue with such testing. It also includes a provision (paragraph 9) permitting Zenith to retain 5 kilograms of raw material for permissible experimentation under the patent laws. Although litigation is now pending to construe the meaning of that consent judgment,[7] the inconsistency between Roche's position in the Valium case and the present case is apparent on its face.

Apart from the foregoing, a search for prior decisions specifically involving the question of whether FDA testing constitutes infringement reveals the existence of only two decisions. In the first case, *Smith, Kline & French Laboratories v. A.H. Robins Co.*, 61 F.R.D. 24 (E.D. Pa. 1973), SK&F, a large research-oriented pharmaceutical company which owns many patents, moved to strike a claim of patent infringement, as a matter of law, on the ground that the manufacture or use of a patented drug product for the purpose of conducting tests to obtain FDA approval is an experimental use and not an infringement. The SK&F motion was denied only because the court lacked evidence as to whether the FDA approval process involved any distribution

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7. *Roche Products, Inc. v. Zenith Laboratories, Inc.*, Civil Action No. 84-2754 (D.N.J.).

of the patented drug which was arguably commercial. Here, it is stipulated that no such distribution occurred.

In the second case, *Pfizer v. International Rectifier Co.*, 217 U.S.P.Q. 157 (C.D. Cal. 1982), experimental use was asserted as a defense to a contempt proceeding involving alleged violations of an injunction against patent infringement. The defendant in *Pfizer* had engaged in a variety of clearly commercial activities in addition to alleged FDA experimentation, and the District Court's discussion of the experimental use issue was dicta. For that reason, the *Pfizer* decision was ignored by both the District Court and the Federal Circuit in reaching their respective and differing decisions in this case.

In summary, every available objective fact establishes that generic drug manufacturers have openly and publicly engaged in pre-patent expiration FDA testing activities, and that drug patent owners have long acquiesced in such testing. The obvious reason for that circumstance is that no one believed that such testing harmed any legitimate or protectable interest of a patent owner. The Federal Circuit should have been guided by this rather clear indication of the *de minimis* nature of the alleged offense. Instead, it chose to treat a patent as an inviolable property right which is entitled to enforcement without regard to economic harm. The court's narrow viewpoint is highlighted by its refusal to credit the candid admission by Roche's counsel that the monetary harm suffered by Roche as a result of Bolar's testing was nominal.

CONCLUSION

This case involves an important question as to the proper balance between the rights of patent owners and the rights of the public. It was decided below in a manner which upsets both the settled expectations of the affected industry and the consistent policy of this Court in preventing attempts to extend the life of a patent. Accordingly, the requested writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A

GENERIC DRUG TESTING AND APPROVAL PRIOR TO EXPIRATION OF PATENT ON BRAND NAME DRUG

BRAND NAME DRUG (Generic Drug)	PATENT OWNER FIRM Generic Firm	DOSE	FDA Application Submission with test data	Date Of FDA Application Approval	Patent Expiration
LIBRIUM (Chlordiazepoxide HCL)	ROCHE	5 mg	12/59	4/60	7/76
		10 mg	12/59	2/60	
		25 mg	12/59	5/60	
	Barr	10 mg	7/72	6/76	
	Zenith	5-10 mg	5/73	3/75	
	Parke Davis	5-10 mg	12/74	8/76	
	Mylan	10 mg	12/74	3/76	
DARVON (Propoxyphene HCL)	LILLY	32-65 mg	3/57	8/57	12/72
	Zenith		1/71	11/71	
	Lederle		7/71	9/72	
	Danbury		2/72	8/72	
	Roxane		6/72	8/73	
	Cord		7/72	10/72	
	Bolar		7/72	12/72	
ORANASE (Tolbutamide)	UPJOHN		8/56	5/57	1/78
	Warner Lambert		9/77	11/79	
	Mylan		6/78	4/79	
	Chelsea		10/77	1/79	
	SKF		11/77	8/79	
	Cord		4/78	6/80	
	Zenith		7/79	3/80	

Appendix A

ALDACTA-ZIDE (Hydro-cholorothazide)	SEARLE		9/60	9/62	12/78
	Bolar		7/77	2/79	
	Chelsea		8/77	4/81	
	Mylan		7/78	8/79	
	Cord		1/79	7/80	
	Zenith		4/79	5/80	
	Barr		2/80	4/81	
HYGROTON (Clorthalidone)	USV	100 mg	1/60	4/60	9/79
		50 mg	1/60	7/67	
		25 mg	12/77	9/79	
	Mylan	50 mg	1/79	2/81	
		25 mg	11/79	2/81	
	Bolar	25 mg	6/79	3/81	
		50 mg	5/79	3/81	
	Zenith	50 mg	10/79	4/81	
	Barr	25-50 mg	3/80	3/81	
PERSANTINE (Dipyridamole)	BOEHRINGER-INGELHEIM	25 mg	4/61	12/61	4/79
	Pharmadine		1/79	9/79	
	Premo		2/79	10/79	
	Cord		3/79	8/80	
	Bolar		4/79	9/79	
	Zenith		4/79	9/79	
	Chelsea		6/79	9/79	
	Par		7/79	9/79	
MELLARILL (Thioridazine)	SANDOZ	10-25 mg	12/58	5/59	3/83
		100-150 mg			
		50 mg	12/58	6/70	

Appendix A

		200 mg	12/58	5/61	
	Mylan	10-25-50 mg	6/82	3/83	
	Cord	10-25-50 mg	9/82	8/83	
	Zenith	50 mg	11/82	4/83	
DIABINASE (Chlorpropamide)	PFIZER		8/58	10/58	10/84
	Premo		3/75	7/80	
	Chelsea		11/79	10/80	
	Pharmadine		2/80	11/80	
	Zenith		6/80	6/81	
	Par		10/82	2/84	
VIBRAMYCIN (Doxycyline)	PFIZER	50 mg	6/66	12/67	8/82
		100 mg	6/66	8/68	
	Rachelle		2/73	7/73	
	Chelsea		8/78	8/81	
	Danbury		12/76	2/77	
	Lemmon		6/79	12/79	
	Barr		9/82	1/83	
	Mylan		10/81	3/82	
ALDOMET (Methyldopa)	MERCK	125 mg	12/73	1/75	9/84
		250 mg	2/62	12/62	
	Cord	250 mg	1/83	6/84	
		500 mg	1/83	6/84	

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

(Hon. Frederick B. Lacey)

Civil Action
No. 75-2221

HOFFMAN-LA ROCHE INC., a corporation,

Plaintiff,

-vs-

ZENITH LABORATORIES, INC., a corporation,

Defendant.

CONSENT JUDGMENT

WHEREAS, the above entitled action was brought by Hoffman-La Roche Inc. (hereinafter "Roche"), as plaintiff, against Zenith Laboratories, Inc. (hereinafter "Zenith"), as defendant, charging Zenith with having taken steps and made arrangements and preparations to infringe United States Letters Patent No. 3,371,085, owned by Roche, and with infringement thereof; and

WHEREAS, Zenith has answered the complaint, denying the aforesaid allegations, and has asserted affirmative defenses including absence of a case or controversy, that the Court ought not to exercise its discretionary jurisdiction because the threat

of infringement by Zenith is too speculative and abstract, that Zenith's application to the United States Food and Drug Administration for approval to market and distribute diazepam is privileged, that Roche is barred from obtaining any remedy in this Court for Zenith's actions by reason of 28 U.S.C. §1498(a), and that Roche is precluded from enforcing said patent because the same is invalid and void for failure to meet the statutory requirements for issuance thereof, for misuse of the patent and for violation of the antitrust laws of the United States; and

WHEREAS, Zenith has asserted counterclaims against Roche alleging a malicious course of conduct to harass Zenith, unfair competition and restraint of trade in violation of the antitrust laws of the United States and of the common law of the State of New Jersey, and has sought relief including treble damages and judgment that Zenith's activities in connection with its importation of diazepam, its FDA application and sale to the United States Government do not constitute patent infringement; and

WHEREAS, Zenith has acknowledged, and by its consent hereto does hereby acknowledge, that upon entry of this Judgment, it will deliver up to Roche from the United States, its territories and possessions, all diazepam in its possession, custody or control, in bulk form for which it shall be reimbursed by Roche in the amount of twenty-five thousand dollars ($25,000); F.O.B. our plant in the Virgin Islands and

WHEREAS, Roche has replied to Zenith's counterclaims, denying all allegations of illegality, impropriety, inequitable conduct and liability contained therein, and has asserted affirmative defenses including that the Court lacks jurisdiction over the second counterclaim; and

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WHEREAS, discovery has been conducted on the issues framed by the complaint, answer, affirmative defenses, counterclaims and replies thereto, and the parties have additionally had the benefit of prior discovery of each other in Civil Action No. 75-96 in this Court; and

WHEREAS, Zenith has acknowledged, and by its consent hereto does hereby acknowledge, that said United States Letters Patent No. 3,371,085 are good, valid and enforceable; that diazepam is disclosed and claimed in said Letters patent; and that Roche is the owner of said Letters Patent and is solely entitled to recover for infringement of said Letters Patent; and

WHEREAS, Zenith has acknowledged, and by its consent hereto does hereby acknowledge, that Zenith has imported into the United States, its territories or possessions, a quantity of diazepam is excess of 500 kilograms (more than half a ton); that Zenith has manufactured, from a part thereof, pharmaceutical dosage form units suitable for administration to humans, including some 100,000 tablets each containing two milligrams of diazepam as the active ingredient, some 100,000 tablets each containing five milligrams of diazepam as the active ingedient, and some 100,000 tablets each containing ten milligrams of diazepam as the active ingredient; that Zenith has used several thousand of said tablets for the purpose of obtaining data and information demonstrating the pharmacological efficacy and suitability for administration of such tablets to humans, the portion so used amounting to approximately 0.19 kilogram of diazepam (less than 0.04% of the amount imported); that Zenith's remaining stock of diazepam is sufficient for it to manufacture more than 250,000,000 tablets each containing two milligrams of diazepam as the active ingredient; that Zenith has made application to the United States Food and Drug Administration for approval to market and

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distribute diazepam in dosage unit form of tablets containing two milligrams, five milligrams, or ten milligrams of diazepam as the active ingredient, and has pursued said application by, *inter alia*, submitted data and information, including that described above, in support thereof; that Zenith's aforesaid acts have all been without leave or license of Roche; and that Zenith has never received the authorization or consent of the United States Government to use or manufacture diazepam in dosage unit form or otherwise; and

WHEREAS, new management has assumed responsibility for the decision making process in Zenith and that management has chosen not to continue with the litigation or contest the validity of Roche patents, the subject of this litigation and desires to settle this litigation; and

WHEREAS, Zenith has acknowledged, and by its consent hereto does hereby acknowledge, that the invention disclosed and claimed in said Letters Patent No. 3,371,085 is the invention of Earl Reeder and Dr. Leo Henryk Sternbach, that it was made by them in this country and that said invention is a pioneer invention; and

WHEREAS, Zenith desires to continue in its experimentation with diazepam as hereinafter provided, and will retain in its possession for such use only five (5) kilograms of diazepam; and

WHEREAS, Zenith has represented, and by its consent hereto does hereby represent, that it will not make, use or sell diazepam, either alone or in conjunction with others, and will not assist, aid or abet others to make, use or sell diazepam, in bulk or dosage unit form, either pure or in admixture with other compounds, including excipients, without leave and license of Roche, on or

after the date of this Judgment and until expiration of said Letters patent on February 27, 1985; and

WHEREAS, Zenith has acknowledged, and by its consent hereto does hereby acknowledge, that it consents to entry of this Judgment as its free act and deed, without coercion or duress, and that there are no agreements or understandings between the parties, except as part of this Judgment;

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. That this Court has jurisdiction over the parties and the subject matter of this action.

2. That United States Letters Patent No. 3,371,085, issued to Roche on February 27, 1968, are good, valid and enforceable, and that Roche is the owner of said Letters Patent and solely entitled to recover for any infringement thereof.

3. That Zenith, each and every subsidiary thereof and each and every company under its direct or indirect control, their officers, agents, servants, employees, successors and assigns, be, and each of them hereby is, enjoined and restrained, for the duration of said Letters Patent No. 3,371,085 through and including February 27, 1985, from

(a) infringing United States Letters Patent No. 3,371,085 or aiding, assisting or abetting others to infringe said Letters Patent;

(b) inducing or contributing to the infringement by others of United States Letters Patent No. 3,371,085;

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(c) making, using, selling, offering for sale, delivering, formulating, encapsulating, tableting, advertising, importing or otherwise obtaining diazepam, or any other substance covered by any claim or claims of United States Letters Patent No. 3,371,085, without leave and license of Roche;

(d) making, using, selling, offering for sale, delivering, formulating, encapsulating, tableting, advertising, importing or otherwise obtaining any product containing diazepam or any other substance covered by any claim or claims of United States Letters Patent No. 3,371,085 as an active ingredient, without leave and license of Roche; and

(e) making, using or selling diazepam, or any other substance covered by any claim or claims of said Letters Patent No. 3,371,085, either alone or in conjunction with others, and will not assist, aid or abet others to make arrangements or preparations for, or take steps, to make, use or sell diazepam, or any other substance covered by any claim or claims of said Letters Patent No. 3,371,085, without leave and license of Roche.

4. That nothing herein shall be construed as limiting, expanding or otherwise affecting any applicability of Title 28, United States Code, Section 1498(a), to Zenith's past or future activities.

5. That nothing herein shall be taken as a waiver or limitation of Roche's right to seek remedy for any sales by Zenith to the

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United States Government, or others; and nothing herein shall be taken as the grant of a license, or as the grant or waiver of any rights by Roche.

6. That the answer, affirmative defenses and counterclaims filed by Zenith be dismissed with prejudice in all respects.

7. That no cost, disbursements, attorneys' fees or damages be awarded.

8. That all terms and conditions of this Judgment shall apply to Zenith and each and every subsidiary thereof and each and every company under its direct or indirect control.

9. Zenith may retain in its possession five (5) kilograms of diazepam for the limited purpose of such experimentation as fairly falls within permissible experimentation under the patent laws of the United States. Nothing herein shall prejudice Zenith from taking advantage of its rights, if any, under Title 28 U.S.C. §1498(a). Nothing contained herein [and in particular by way of illustration and not limitation, Paragraphs 3(c), 3(d) and 3(e)] shall be construed as limiting, expanding or otherwise affecting the provisions of this Paragraph 9.

ENTERED as of this 2nd day of August, 1979,

s/ Frederick B. Lacey
United States District Judge

Form, Entry and Substance of the foregoing
Judgment are hereby consented to:

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ZENITH LABORATORIES, INC.

By: (illegible)
President

[CORPORATE SEAL]
Attest:

By: (illegible)
Secretary

SILLS, BECK, CUMMIS,
RADIN & TISCHMAN, P.A.

By: (illegible)
A Member of the Firm
Attorneys for Zenith
Laboratories, Inc.

HOFFMAN-LA ROCHE INC.

By: Ellis B. Anderson
Vice-President

[CORPORATE SEAL]
Attest:

By: (illegible)
Assistant Secretary

CRUMMY, DEL DEO,
DOLAN & PURCELL

Appendix B

By: (illegible)
A Member of the Firm
Attorneys for Hoffman-
La Roche Inc.